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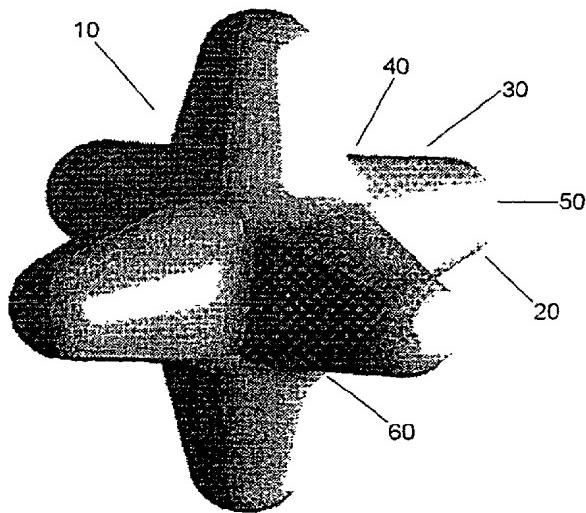
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(54) Title: SHAPED PARTICLE AND COMPOSITION FOR BONE DEFICIENCY AND METHOD OF MAKING THE PARTICLE



**WO 01/066044 A3**

(57) Abstract: A shaped particle (10) for use in an array of interlocking particles to repair, replace, improve or augment a bone deficiency is provided. The particle in a preferred embodiment has six extremities (20), and the interstitial spaces (60) between the extremities(20) of one particle accept the extremities of an adjacent particle in an array. The particle is suspended in a material which facilitates application of the particle to bone, and the material may contain biological factors which augment bone growth or prevent infection. Furthermore, a method of making a shaped particle by producing a hardened calcium sulfate material is provided.



- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

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# INTERNATIONAL SEARCH REPORT

International Application No  
PCT/US 01/06043

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61F2/28 A61L27/02 A61L27/10 A61L27/56 C01F11/46

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61F A61L C01F C04B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, PAJ, WPI Data

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 676 700 A (SEREKIAN PAUL ET AL) 14 October 1997 (1997-10-14) cited in the application column 1, line 7 -column 4, line 47 claims; figures	1,2,4-6, 9,14-23, 26
A	---	3,7,8, 10-13, 24,25, 27-44, 47-59
X	WO 94 08912 A (USHERS INC) 28 April 1994 (1994-04-28) cited in the application claims; figures	1-5, 14-21, 23,26
A	---	24,27-32
		-/-

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

### ° Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
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- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "&" document member of the same patent family

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International Application No  
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## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 178 201 A (AHLERS OLAF) 12 January 1993 (1993-01-12) cited in the application column 2, line 38 -column 3, line 20 claims; figures ---	1-3,26, 60
A	US 5 258 028 A (ERSEK ROBERT A ET AL) 2 November 1993 (1993-11-02) cited in the application column 1, line 11 - line 26 column 2, line 36 - line 54 column 3, line 50 - line 60 column 4, line 27 - line 44 column 9, line 38 -column 10, line 22 claims; figures ---	1-44, 47-60
A	WO 99 18894 A (PARALLAX MEDICAL INC) 22 April 1999 (1999-04-22) claims ---	1-44, 47-60
P,A	WO 00 74690 A (WRIGHT MEDICAL TECH INC) 14 December 2000 (2000-12-14) claims; examples ---	1-44, 47-60
P,A	WO 01 03709 A (CAP BIOTECHNOLOGY INC) 18 January 2001 (2001-01-18) claims ---	1-44, 47-60
X	DE 33 22 970 A (QUANTE HEINRICH) 9 February 1984 (1984-02-09) page 5 -page 8, paragraph 1 page 11, paragraph 3 -page 12, paragraph 1 claims 1-6,9,14 ---	61-63
Y	US 6 030 636 A (RANDOLPH DONALD A ET AL) 29 February 2000 (2000-02-29) claims 9,12,17-25,27,29; figures 7-9; examples 1,5 ---	61-63
Y	US 3 410 655 A (EGON CHERDRON ET AL) 12 November 1968 (1968-11-12) claims; examples ---	61,62
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A	GB 1 224 149 A (CONZIC RIOTINTO OF AUSTRALIA LTD) 3 March 1971 (1971-03-03) page 1, line 25 - line 34 page 2, line 1 - line 30 claims 1-10 ---	61,62
		-/-

## INTERNATIONAL SEARCH REPORT

International Application No  
PCT/US 01/06043

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 320 677 A (BAIG MIRZA A) 14 June 1994 (1994-06-14) cited in the application claims; figures ---	61,62
A	LEA F M: "THE CHEMISTRY OF CEMENT AND CONCRETE" 1970 , EDWARD ARNOLD LTD , LONDON, GB XP002200941 page 18 -page 19 -----	61-63

## INTERNATIONAL SEARCH REPORT

### Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1.  Claims Nos.: 45 46 because they relate to subject matter not required to be searched by this Authority, namely:  
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2.  Claims Nos.: because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3.  Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

### Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1.  As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2.  As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3.  As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4.  No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

#### Remark on Protest

The additional search fees were accompanied by the applicant's protest.

No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-44 47-60

A shaped particle for use in treating a bone deficiency for using in an array of particles interlocked with one another.

2. Claim : 61

A method for manufacturing a shaped particle of calcium sulphate dihydrate comprising:  
making shaped particle of calcium sulphate dihydrate;  
heating said particle;  
applying water to said particle.

3. Claim : 62

A method for manufacturing a shaped particle of calcium sulphate dihydrate comprising:  
making shaped particle of calcium sulphate dihydrate;  
heating in presence of pressure and moisture said particle of calcium sulphate dihydrate to convert said particle to alpha-calcium sulphate hemihydrate partially or in full;  
applying water to said particle to convert said alpha-calcium sulphate hemihydrate to calcium sulphate dihydrate.

4. Claim : 63

A method for manufacturing a shaped particle of calcium sulphate dihydrate comprising:  
making shaped particle of calcium sulphate dihydrate;  
heating in presence of pressure and moisture said particle of calcium sulphate dihydrate to convert said particle to beta-calcium sulphate hemihydrate partially or in full;  
applying water to said particle to convert said beta-calcium sulphate hemihydrate to calcium sulphate dihydrate.

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